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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/403,803	03/17/1995	RON S. ISRAELI	41426-A-PCT-	4181

7590 12/15/2003
JOHN P WHITE
COOPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/403,803

Applicant(s)

ISRAELI ET AL.

Examiner

Stephen Gucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 100-105 and 113-126 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 116-119 is/are allowed.
- 6) ☒ Claim(s) 100-105, 113-115 and 120-126 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 0.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. Claims 100-105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record and the following. Claims 100-105 are indefinite because they do not recite the specific hybridization conditions which Applicant regards as being specifically hybridizing to a nucleic acid sequence of SEQ ID NO:1. Whether or not specific hybridization occurs is a function of the hybridization conditions such as specific ionic strength, specific temperature, specific number of washings, etc. and therefore "hybridizes specifically" or "specifically hybridizes" as recited in the claims encompass a variety of conditions which will vary depending on the specific nucleotide sequence structures which are being claimed, i.e. length of sequences, G/C content of sequences, number and amount of competing or similar sequences in a particular sample, etc., and these claimed hybridizing sequences can only be adequately defined by specifically reciting hybridization conditions.
4. *Applicant's arguments filed 8/14/03 have been fully considered but they are not persuasive. Applicant's arguments are drawn to references that teach, in*

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general, how to calculate and set specific hybridization conditions in order that specific probes of a specific sequence can hybridize to a target sequence. However, the product claims are drawn to a genus of nucleic acid sequences of 15 nucleotides or longer in length whose actual chemical structure or sequence is only defined by the process of hybridizing to instant SEQ ID NO:1. As set forth in the original rejection, the metes and bounds of this genus are determined solely by the specific hybridization conditions employed. Therefore, these products by process claims remain indefinite unless the specific process, i.e. hybridization conditions used to define the process, and therefore the products, are explicitly recited in the instant claims. While the terms "specifically hybridizes" or "hybridizes specifically" are understood by scientists qualitatively, what is required in the instant claims are the quantitative aspects of the specific hybridization such as temperature and ionic strength that clearly and unambiguously set forth the boundaries of the claim so the public could understand from the hybridization conditions recited which nucleic acid sequences were encompassed by the claimed genus and which sequences would not be encompassed.

5. Claims 100-102, 113-115, and 120-121 are rejected under 35 U.S.C. 102(a) as being anticipated by Sulavik et al. ("Sulavik") for reasons of record and the following. Sulavik discloses GenBank sequence accession number M89776 (pages 3579 and 3582) whose nucleotides encode amino acids 60-67 of instant SEQ ID NO:2. An eight amino acid peptide is of sufficient length to be antigenic and this entire sequence can selectively hybridize to SEQ ID NO:1 under very

low stringency conditions since the conditions recited in the instant claims are not defined.

6. Claims 100-102, 113-115, and 120-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Palm et al. ("Palm"). Palm discloses the nucleotide sequence of virus SSV1 (pages 244-245) whose nucleotides encode amino acids 62-68 of instant SEQ ID NO:2. A seven amino acid peptide is of sufficient length to be antigenic and this entire sequence can selectively hybridize to SEQ ID NO:1 under very low stringency conditions since the conditions recited in the instant claims are not defined.

7. Claims 100-102, 113-115, and 120-126 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramakrishnan et al. ("Ramakrishnan"). Ramakrishnan discloses the nucleotide sequence of ribosomal protein L18 from *Bacillus stearothermophilus* (page 883) whose nucleotides encode amino acids 101-107 of instant SEQ ID NO:2 (see attached sequence comparison and enlarged page at end of this publication). A seven amino acid peptide is of sufficient length to be antigenic and this entire sequence can selectively hybridize to SEQ ID NO:1 under very low stringency conditions since the conditions recited in the instant claims are not defined.

Applicant's arguments filed 8/14/03 against all prior art rejections set forth above have been fully considered but they are not persuasive. The prior art references need not teach a specific sequence that is an exact match in sequence identity to instant SEQ ID NO:1. Under low hybridization conditions, considerable mismatch can occur between the hybridizing sequences; the

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sequences do not have to share 100% sequence identity. It is noted that Applicant's claims are broader than merely encompassing sequences that are fragments of either SEQ ID NO:1 or its complementary sequence, so Applicant's arguments concerning mismatches are clearly not persuasive since Applicant is intending to encompass with the instant claims sequences and fragments of sequences that do not share 100% identity to either SEQ ID NO:1 or fragments of SEQ ID NO:1. Claims limited to such 100% matching sequences have already been allowed (instant claims 116-119), and by the rules of claim differentiation, the instant claims under rejection are different in scope from allowed claims 116-119. Furthermore, the Examiner is asserting that under low hybridization conditions, the whole sequence taught in the prior art, and not some species of a genus, meets the limitations of the instant claims. Finally, Applicant argues that the prior art sequence would hybridize more strongly to other sequences than they would to instant SEQ ID NO:1, which the Examiner agrees is a true statement. This argument is not persuasive, however, because this is not a limitation recited in the instant claims. "Hybridizes specifically" is a vague and qualitative statement and varies considerably from experimental situation to experimental situation. Specifically defining the hybridization conditions and reciting such conditions in the claims quantitatively could obviate the grounds of these prior art rejections.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

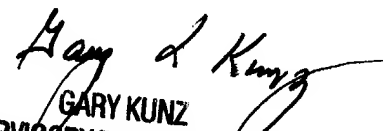
9. Claims 116-119 are in condition for allowance.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Stephen Gucker

12/11/03


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600